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IS 3318 (1965): General requirements for surgical scalpels and knives [MHD 1: Surgical Instruments]

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GENERAL REQUIREMENTS FOR
SURGICAL SCALPELS AND KNIVES

(Incorporating Amendment No. 1)

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Price Group 2

Indian Standard

GENERAL REQUIREMENTS FOR SURGICAL SCALPELS AND KNIVES

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Indian Standard

GENERAL REQUIREMENTS FOR SURGICAL SCALPELS AND KNIVES

0. F O R E W O R D

0.1 This Indian Standard was adopted by the Indian Standards Institution on 27 October 1965, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Consumer Products Division Council.

0.2 This Indian Standard is one of a series on Surgical Scalpels formulated at the instance of the Advisory Committee for Surgical Instruments, Medical Equipment and Hospital Appliances of the Ministry of Industry and Supply, Government of India. Other specifications published so far in the series are:

IS : 3319-1965 Surgical scalpels with detachable blades

IS : 3320-1965 Surgical scalpels

0.3 This standard covers the requirements for scalpels and knives which are general and common between the various types coming under these categories. Individual specifications which include specific requirements for different scalpels and knives are covered in separate standards. The provisions of this standard are such as to help providing a correct balance of the instrument when the surgeon handles it.

0.4 The recent trend in the manufacture of scalpels and knives is to eliminate the plating of handles. However, due to difficulty of procuring raw materials, that is stainless steel; brass, nickel silver, etc, has also been specified with the provision of plating. For the choice of materials for handles of such scalpels, therefore, reference is made to **2.5** of this standard.

0.5 In preparing this standard, considerable assistance has been derived from the following:

57-GP-1 Specification for knives, surgical, handles and detachable blades. Canadian Government Specifications Board.

DIN 58250 Operations skalpelle. Deutscher Normenausschuss.

IND/GS/MED/664(a) Knife bard parker blade No. 10, 11, 12, 15, 20, 22 and 23. Chief Inspectorate of General Stores, Ministry of Defence, Government of India.

IND/GS/MED/725(a) Knife bard parker handle No. 3, 4 and 7. Chief Inspectorate of General Stores, Ministry of Defence, Government of India.

IND/GS/MED/1022 Specification for scalpel 5 cm. Chief Inspectorate of General Stores, Ministry of Defence, Government of India.

IND/GS/MED/1023 Specification for scalpels sizes 3 and 6. Chief Inspectorate of General Stores, Ministry of Defence, Government of India.

B.S. 2820 : 1957 Surgical scalpels. British Standards Institution.

B.S. 2982 : 1958 Scalpel with detachable blades. British Standards Institution.

0.6 This edition 1.1 incorporates Amendment No. 1 (April 1969). Side bar indicates modification of the text as the result of incorporation of the amendment.

0.7 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers the general requirements for different kinds of scalpels and knives used in surgical work.

2. MATERIALS

2.0 The materials used in the manufacture of scalpels and knives shall be as follows.

2.1 Blades Detachable — The composition of steel for detachable blades shall conform to Designation T118Cr45 of IS : 1570-1961 Schedules for Wrought Steels for General Engineering Purposes.

2.2 Blades and Handles, Hand Forged Together — The composition of steel for scalpels and knives when hand forged shall be as follows:

Carbon	1.0-1.5 percent
Silicon	0.25 percent, <i>Max</i>
Manganese	0.30 percent, <i>Max</i>
Sulphur	0.030 percent, <i>Max</i>
Phosphorus	0.030 percent, <i>Max</i>

*Rules for rounding off numerical values (*revised*).

2.3 Handles, Drop Forged — The composition of steel for scalpels and knives when drop forged, but leaving a block end for further processing by hand, shall be as follows:

Carbon	0.80-0.85 percent
Silicon	0.10-0.35 percent
Manganese	0.20-0.40 percent
Sulphur	0.025 percent, <i>Max</i>
Phosphorus	0.035 percent, <i>Max</i>
Chromium	0.10-0.40 percent

2.4 Stainless Steel for Blades and Handles — The composition of stainless steels for scalpels and knives shall be as follows:

1) Carbon	0.95-1.20 percent
Silicon	1.00 percent, <i>Max</i>
Manganese	1.00 percent, <i>Max</i>
Sulphur	0.045 percent, <i>Max</i>
Phosphorus	0.045 percent, <i>Max</i>
Chromium	16.00-18.00 percent
2) Carbon	0.9 to 1.10 percent
Silicon	0.35 percent, <i>Max</i>
Manganese	0.6 to 0.8 percent
Chromium	12.0 to 14.5 percent
Nickel	0.5 percent, <i>Max</i>
Sulphur	0.03 percent, <i>Max</i>
Phosphorus	0.03 percent, <i>Max</i>
Molybdenum	1.5 to 1.8 percent

2.5 Handles — Handles when separately fabricated shall be made from the following materials:

1. Stainless steel	Designation 07Cr19Ni9 of Schedule V of IS : 1570-1961*
2. Brass	Grade 1 conforming to IS : 291-1961†
3. Nickel silver	CuNi20Zn22 conforming to IS : 2451-1963‡

2.5.1 The brass and nickel silver handles shall be plated chromium over nickel.

2.5.2 The plating shall conform to Grade B of IS : 1068-1958§.

*Schedules for wrought steels for general engineering Purposes.

†Specification for naval brass rods and sections (suitable for machining and forging) (*revised*).

‡Specification for nickel silver ingots and castings for cutlery and hollow-ware.

§Specification for copper nickel and chromium electroplated coatings.

3. DIMENSIONS

3.1 The dimensions of scalpels and knives shall be in accordance with the requirements of individual specifications, unless otherwise specified by the purchaser.

4. MANUFACTURE

4.1 Scalpels and knives shall be made by the following methods:

- a) Detachable blades, hand forged or stamped from plate or strip;
- b) Hand forged completely from one piece of steel;
- c) Drop forged, leaving block ends, the block ends being hand forged into the shape of the blades; and
- d) Cold pressed after copy turning.

4.2 The scalpels and knives shall be so forged as to be uniform on their central planes with the cutting edge on the central plane itself. The blade portion except in the case of detachable blades, shall be hollow-ground to the curvature specified in individual standards unless otherwise required by the purchaser. The detachable blades of scalpels shall have the cutting edge central in respect of its thickness and be in one plane.

5. HARDENING

5.1 The blades of surgical scalpels and knives shall be hardened and tempered to 700 to 800 *HV* and the detachable blades to 800 to 850 *HV*.

6. FINISH

6.1 The blade shall be highly polished and free from any blemishes. All edges except the cutting edge shall be rounded. The cutting edge shall be surgically sharp and free from feathers, nicks, high spots, waviness or undulation. The handle shall be finished smooth with a matt surface. It shall be free from burrs, sharp or rough edges, pits and other surface defects. The edge shall be chamfered.

7. MARKING

7.1 The scalpels and knives shall be clearly and indelibly marked with the manufacturer's name, trade-mark or identification mark. When the marking is done on the blade portion, it shall be done by electro-etching.

7.1.1 The scalpels and knives may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act, and the Rules and Regulations made thereunder. Presence of this mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard, under a well-defined system of inspection, testing and quality control during production. This system, which is devised and supervised by ISI and operated by the producer, has the further safeguard that the products as actually marketed are continuously checked by ISI for conformity to the standard. Details of conditions, under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

8. TEST

8.1 The cutting edge shall be examined under a magnification of at least 60 X in two directions along and perpendicular to the plane of the cutting edge, and it shall not reveal any feather edge, nick, high spot, waviness or undulation.

8.2 The scalpels and knives shall be tested by cutting a piece of Chamois leather with moderate pressure at least five times. They shall cut easily and clearly along the entire length of the cutting edge. On completion of the test, the scalpel or knife shall show no sign of damage, when examined in accordance with **8.1**.

9. PACKING

9.1 Scalpels and knives shall be packed in accordance with the requirements of individual specifications.

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